

## **Remarks**

### **Status of the Application**

The Office conducted a telephone interview with Applicant on 10/20/2004, following which Applicant submitted an Amendment on 10/29/2004.

In the present Office Action:

The Office rejected Claims 1-16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention. Office Action page 1 line 7 – page 2 lines 21.

The Office rejected Claim 17 under 35 U.S.C. 102 as anticipated by *Zolla-Pazner et al.* Office Action page 2 line 22 – page 3 line 5.

The Office made the rejection final. Office Action page 3 lines 10-24.

Applicant submitted a proposed Amendment to the Office, which was followed by a telephone interview on 3/8/2005.

### **Summary of 3/8/2005 Telephone Interview**

A proposed response was faxed to the examiner on February 8, 2005. The amendments to the Claims in this Amendment are the same as those in the proposed response. After rescheduling several times at the examiner's request, a telephone interview with Examiner Parkin was conducted on 3/8/2005.

With respect to Claim 1. The examiner indicated the proposed amendment cured the rejection under 35 U.S.C. 112 from page 1, third paragraph of the Office Action. The examiner noted that he would discuss the claims with his supervisor at a later time.

With respect to Claim 8. The examiner indicated the amendment cured the rejection under 35 U.S.C. 112 found on page 2, first paragraph of the Office Action.

With respect to Claim 11. The examiner asserted that the proposed amendment did not cure the rejection under 35 U.S.C. 112.

### **Finality of the Rejection, and Entry of the Present Amendment**

The Office made the present rejection final, asserting that Applicant's amendments necessitated any and all new grounds of rejection. Applicant submits that this assertion is incorrect. The Office rejected the Claims under 35 U.S.C. 112 in the 6/5/2004 Office Action. In the 10/20/2004 telephone interview, the Office indicated that the amendments that were formalized in the 10/29/2004 Amendment would cure the corresponding rejections. The Office now asserts that the 10/29/2004 amendments, agreed by the Office to cure the rejections under 35 U.S.C. 112, necessitate additional rejections under 35 U.S.C. 112. The Office's final rejection is inconsistent with prior communications, and deprives Applicant of the opportunity for a full and fair examination. See MPEP 706.07 ("present practice does not sanction hasty and ill-considered final rejections," "in every case the applicant is entitled to a full and fair hearing").

Further, the Office's late assertion of new rejections under 35 U.S.C. 112 in a final rejection deprive the Applicant of the opportunity to either bring the Claims into compliance with the Office's requirements or

develop a clear issue for appeal. See MPEP 706.07 ("The applicant ... should ... not be prematurely cut off in the prosecution;" "a clear issue between applicant and examiner should be developed, if possible, before appeal").

In the present Office Action, the Office identified specific aspects of the Claims that the Office believes were confusing, and suggested specific corrections:

Claims 1 and 11. The Office asserted that there was a possible confusion as to whether the **combination** step combined **samples or values from measurements**. The Office required correction to clarify that the combination was of values from measurements. Office Action page 1 lines 21-30; page 2 lines 10-21. The present amendments to Claims 1 and 11 make no changes other than to comply with the Office's required correction.

Claim 8. The Office indicated confusion stemming from naming conventions adopted in the claim. Office Action page 2 lines 1-9. The present amendment to Claim 8 makes no change to Claim 8 other than to adjust the naming conventions to preclude the confusion asserted by the Office.

Claim 17. The only art-based rejection in the present Office Action was of Claim 17. The present amendment cancels Claim 17.

The present Amendment (i) cancels the only claim subject to an art rejection, and (ii) adopts the Examiner's requirements for correction of certain wording, and accordingly should be entered. See 37 CFR 1.116 ("amendments may be made canceling claims or complying with any requirement of form expressly set forth in a previous Office action"); MPEP 714.12. Even if the Office asserts that the present amendments are more than compliance with the Office's requirements, the present amendments do address the Office's asserted confusion, clarifying the issues for appeal. See 37 CFR 1.116 ("amendments presenting rejected claims in better form for consideration on appeal may be admitted"); MPEP 714.12.

Accordingly, Applicant requests that the present amendment be entered to present a clearer issue for appeal, or, in the alternative, that the finality of the present Office Action be withdrawn and the present amendment entered.

#### **Rejection of Claims 1 and 11 under 35 U.S.C. 112**

The Office indicated that Claims 1 and 11 could be confusing, since the wording could be construed to indicate the combination of **samples** or cells instead of the combination of **results** from measuring number of cells. Applicant respectfully traverses this rejection, since the Claims, read in light of the Specification, are clear that the combination is of the measurement results and not of the samples. The Office cited a specific portion of the specification that made this issue clear. See Office Action page 1 lines 21-29.

However, in the interests of expeditious issuance, Applicant has amended Claim 1 to make explicit that the combination is of the **results of the measurements of the cells**, and not of the cells themselves.

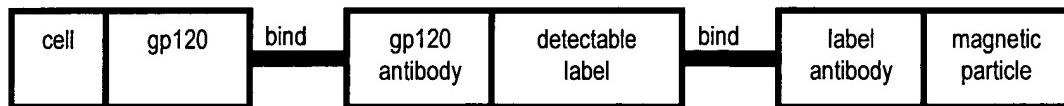
Applicant has amended Claim 11 to make explicit that the combination is of the **measurements of the two fractions**, and not of the fractions themselves. Applicant submits that the amendments remove the

potential confusion identified by the Office, and that Claims 1 and 11, and their corresponding dependent claims, are in condition for allowance.

**Rejection of Claim 8 under 35 U.S.C. 112**

The Office indicated that Claim 8 could be confusing. Applicants believe that the previous wording was not confusing, but, in the interest of expeditious issuance, have amended Claim 8 responsive to the Office's requirement. Specifically, Claim 8, previously and as amended, involves in step (a) forming a mixture. Step (a)(i) specifies that the mixture includes a first antibody, specific to gp120, which first antibody is attached to a detectable label. As the Office notes, such antibodies and labels are known to those skilled in the art. Step (a)(ii) specifies that the mixture includes a second antibody, specific to the detectable label, which second antibody is attached to a magnetic particle. Antibodies that are specific to labels are understood by those skilled in the art. See, e.g., product specifications from VWR and Sigma-Aldrich, representative copies of which are enclosed herewith.

Step (b) specifies that the first antibody (specific to gp120) binds to gp120 on a cell. The second antibody (specific to the label attached to the first antibody) binds to the label. This relationship set forth in Claim 8 is shown schematically below.



Applicant submits that the wording of Claim 8 is clear, and that Claim 8 is in condition for allowance.

**Conclusion**

Applicant has responded to each and every rejection and urges that the Claims as presented are in condition for allowance. Applicant requests expeditious processing to issuance.